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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,900	08/22/2001	John R. Booth	BB1476 US NA	8096

23906 7590 05/05/2004

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EXAMINER

MCCELWAIN, ELIZABETH F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/934,900

Applicant(s)

BOOTH ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims 10-13 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

Claims 1-4, 6, 8, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last office action.

Applicants' arguments filed February 2, 2004 have been fully considered but they are not persuasive. Applicants assert that the specification discloses two delta-9 desaturase genes and it is confirmed that they are diverged delta-9 desaturase genes that encode functional enzymes even though they do not share conserved sequence elements that are associated with delta-9 desaturase activity. Applicants argue that the claimed sequences define a new functional class of plant delta-9 desaturases.

The Examiner maintains that applicants have not defined or described a new functional class of plant delta-9 fatty acid desaturases, yet applicants have claimed an entire genus that encompasses polynucleotides that encode polypeptides having at least 80%, 85%, 90% or 95% identity to SEQ ID NO: 2 based on the Clustal alignment method. However, the specification does not describe what structural features or functional characteristics define said new functional class of plant delta-9 desaturases. In addition, while the claims are limited to sequences having the specified identities to SEQ ID NO: 2 based on the Clustal alignment method, this method can have highly variable results depending on the parameters used, such as the clustal size and the gap length, for example.

“A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” In addition, “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention”. See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

In the instant case neither structural or physical characteristics have been identified that distinguish the claimed genus of delta-9 desaturases from other sequences that fall within the

limitations of the claims. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Claims 1-4, 6, 8, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated for claims 1-9, 14 and 15 in the last office action.

Applicants' arguments filed February 2, 2004 have been fully considered but they are not persuasive. Applicants assert that the specification discloses two delta-9 desaturase genes that were constructed using two known delta-9 desaturase genes and they share a high degree of homology with other known delta-9 desaturases. Applicants argue that the specification provides guidance with regard to evaluating plants transformed with the claimed sequences and for evaluating the expression of diverged delta-9 desaturase genes that encode functional enzymes.

The Examiner maintains that the rejection is proper given that the specification does not provide guidance with regard to evaluating polypeptides for diverged delta-9 desaturase activity, given that it is unclear what diverged activity is and how it would be identified.

Applicants state that they are not relying on sequence identity to identify related sequences encoding enzymes having a particular activity, asserting that the sequences of the

instant invention are shown in Example 10 as having delta-9 desaturase activity, and that Table 5 on page 32 shows the percent identity of polypeptides to a diverged delta-9 or stearyl-ACP desaturase. The Examiner maintains that the specification is enabling for those sequences that have been shown to have delta-9 desaturase activity, but that it would require undue experimentation to determine which other sequences that fall within the scope of the claim would also have delta-9 desaturase activity, particularly in view of the results presented in Table 5, which shows a broad range of sequence identity for delta-9 desaturases.

Furthermore, applicants have claimed an entire genus that encompasses polynucleotides that encode polypeptides having at least 80%, 85%, 90% or 95% identity to SEQ ID NO: 2 based on the Clustal alignment method. However, while the claims are limited to sequences having the specified identities to SEQ ID NO: 2 based on the Clustal alignment method, this method can have highly variable results depending on the parameters used, such as the clustal size and the gap length, for example.

Claims 1-3, 6 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Swiderski et al (Plant Science 151:75-83, 2000 in IDS, see alignment with sequence Accession AF139377, March 17, 2000), as stated in the last office action.

Applicants' arguments filed February 2, 2004 have been fully considered but they are not persuasive. Applicants assert that the rejection should be withdrawn given that using the Clustal alignment method the claimed sequence has only 77.6% identity to the prior art sequence. The Examiner maintains that the claims do not set forth the parameters for sequence

comparisons using the Clustal alignment method and that the use of different parameters, such as clustal size and gap length that a different result would be obtained and the sequence has been shown to have at least 90% sequence identity.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sato et al (Plant Physiol. 99:362-363, 1992).

Applicants' arguments filed February 2, 2004 have been fully considered but they are not persuasive. Applicants assert that the rejection should be withdrawn given that using the Clustal alignment method the claimed sequence has only 60.1% identity to the prior art sequence. The Examiner maintains that the claims do not set forth the parameters for sequence comparisons using the Clustal alignment method and that the use of different parameters, such as clustal size and gap length that a different result would be obtained and the sequence has been shown to have at least 80% sequence identity.

Claims 5, 7 and 9 are objected to for depending on a rejected base claim, but would be allowable if written in independent form.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until

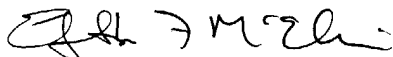
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after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Elizabeth F. McElwain, Ph.D.  
Primary Examiner  
Art Unit 1638

EFM  
April 29, 2004